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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,155	10/01/2001	Ole Sibbesen	078883-0132	9265

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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,155	Applicant(s) SIBBESEN ET AL.	
	Examiner Manjunath N. Rao, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 26-34, 36, 38, 39, 41, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 27-34, 36, 38, 39, 41, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-25-01, 6-22-01, 5/6/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8, 11, 26-34, 36, 38-39, 41, 44-45 are presently pending in this application.

Claim 26 is now under consideration. Claims 1-8, 11, 27-34, 36, 38-39 and 41, 44-45 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 11-25-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Election/Restrictions

Applicants continue to traverse the restriction requirement arguing that claims 26-30 and 44-45 are all linked by a common inventive concept namely the specific xylanase inhibitors and/or use thereof to identify xylanases having a specific degree of resistance thereto.

Applicants also argue that claims 27-30 should be joined as they depend from claim 26, arguing that the principles of "unity of invention" dictate that if an independent claim has unity of invention, claims depending therefrom also have unity of invention, (MPEP AI-63). While Examiner is aware of the PCT rules and instructions concerning Unity of Invention, he respectfully disagrees with above arguments and interpretation of the rules by the applicant.

Claims 27-30, 44-45 clearly are an independent invention and are not linked by a common inventive concept with claim 26 even though applicants have made them to depend from claim 26. This is because claim 26 is directed to the use of a xylanase inhibitor and involves the testing of any or all types of xylanases i.e., those that are resistant and not resistant to the xylanase inhibitor of claim 26. On the other hand claims 27-30, 44-45 are drawn to xylanase

Art Unit: 1652

enzymes and the method of isolating them and using them, specifically only those xylanases that are resistant to the inhibitor. This clearly shows two different inventive entities that are not linked by the same inventive concept. One of the invention is an enzyme inhibitor and the other is an enzyme. Further even in the enzyme invention all enzymes are xylanases that are resistant to the inhibitor and therefore they are clearly not linked by the same inventive concept. Therefore claims 27-30, 44-45 remain withdrawn from consideration as being drawn to non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, 11, 27-34, 36, 39-39 and 41, 44-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 11 and in paper filed on .

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). However, Examiner has not granted the priority date of 12-23-1998 (with reference to UK 9828599, 12-23-1998) as support for the claim now under consideration is found only in foreign priority document UK 9907805, filed 4-6-1999.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26, in lines 1-2 and 13 recites the phrase “having a high degree of resistance” which renders the claim indefinite. It is not clear to the Examiner as to what per cent of inhibition (for example 50%, or 90% or 95%) or how much resistance is considered by the applicant as “high degree of resistance”. A perusal of the specification did not yield a specific a definition for the above phrase. Without a specific quantitative value assigned to the resistance characteristic, the above phrase comprising the term “high” (an open ended term) renders the claim indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 26 is directed to a method of using a genus of polypeptides having xylanase inhibiting activity wherein said polypeptides comprise one or more short amino acid sequences

Art Unit: 1652

SEQ ID NO:13, 14, 15, 16, 17 ,18 and/or 19. The specification does not contain any disclosure of the full length structure of all polypeptide sequences included in the claimed genera. The genus of polypeptides claimed is a large variable genus with the potentiality of having different full length structures. Therefore, many structurally distinct polypeptides are encompassed within the scope of these claims. The specification does not disclose even a single species (full length) of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by full length sequence or a recitation of structural features common to members of the genus, **which features constitute a substantial portion of the genus**. The recited structural feature of the genus (i.e., a polypeptide comprising a fragment of amino acid sequence) does not constitute a substantial portion of the genus as the remainder of the structure of any polypeptide having xylanase inhibiting activity is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Art Unit: 1652

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Debyser (a) et al. (J. Cereal Sci., 1999, Vol. 30:39-43) or Debyser (b) et al. (WO 98/49278, 11-5-1998) or Rouau et al. (J. Cer. Sci., 1998, Vol. 28 :63-70). This rejection is based upon the public availability of a printed publications. Claim 26 of the instant application is drawn to an a method of using a endo- β -1,4-xylanase inhibitor for determining the degree of resistance of xylanases to an inhibitor wherein said inhibitor is isolated from wheat flour, wherein the inhibitor has a molecular weight of about 40 kDa as measured by MS or SDS PAGE, wherein the inhibitor has a pI of about 8 to about 9.5, and wherein the inhibitor comprises one or more amino acid sequences presented as SEQ ID NO:13 through 19 by contacting the enzyme with the inhibitor and determining the activity of the xylanase and identifying those that are resistant to the action of the inhibitor.

Debyser(a) et al. teach a xylanase inhibitor called as TAXI isolated from wheat flour and determine the degree of resistance of the xylanase towards the inhibition as well. Debyser (b) et al. and Rouau et al. also teach a xylanase inhibitor isolated from wheat flour and determine the degree of resistance of the xylanases towards the inhibition. The references teach that the inhibitor has a molecular weight between 40-43 kDa as determined by SDS PAGE. The references do not explicitly disclose the pI values of the inhibitor protein.

Art Unit: 1652

The references clearly teach the importance of xylanase enzymes in the baking industry as well as the importance of its activity in the wheat flour dough. The reference compares several different xylanases in their ability to withstand the action of the inhibitor. However, the references do not explicitly suggest that said inhibitor can be used to identify xylanases that are resistant to its action. Also, the references do not explicitly teach that the inhibitor protein comprises the amino acid sequences with SEQ ID NO:13 through 19. Examiner takes the position that such characteristics of a protein are inherent characteristics and therefore the xylanase inhibitor taught by Debyser(a), (b) et al. and Rouau et al. and that claimed in the above method are one and the same (Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594). Furthermore, based on the teachings of Debyser(a) and (b) et al. that xylanases are industrially important due to their use in bread-making recipes since they have a positive effect on bread volume and that inhibition of such enzyme would be deleterious to the bread-making efforts, Examiner maintains that it would have been obvious to those skilled in the art to devise methods to identify and select enzymes (xylanases) that are resistant to the inhibitor. Such method would have been obvious because the reference also suggests that the inhibitor is inherently present in wheat flour used in the baking bread. One of ordinary skill in the art would be motivated to do so as the above reference teaches that inhibition of the xylanase enzyme would negatively effect the bread volume and that

Art Unit: 1652

the inhibitor is inherently presently in the wheat flour. One of ordinary skill in the art would have a reasonable expectation of success since the above reference uses said inhibitor to analyze several types of xylanases for their ability to be inhibited by the inhibitor.

Therefore the above inventions would have been *prima facie* obvious to those skilled in the art.

Conclusion

None of the claims are allowable.

As Examiner has introduced a new rejection under 35 U.S.C. 112, 1st paragraph, which was not previously presented to applicants Examiner has maintained this Office action as a non-final Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao. Ph.D.
February 18, 2004